APR 14 2006

K051651

510(k) SUMMARY

(As required by 21.CFR.807.92)

Introduction: According to the requirements of 21 CFR.807.92, the following information provides sufficient data to understand the basis for a determination of substantial equivalence.

Submitted By: US Diagnostics, Inc.
304 Park Avenue South
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New York, NY 10010

Contact Person: Edward Letko
Phone: 917-402-5900
Fax: 212-202-5173

Date Summary, Prepared: March 07, 2006

Device Name: Propriety Name: G4™
Common Name: Blood Glucose Test System
Classification Name: Class II, 862.1345 Glucose Blood Tester

Predicate Device: We claim substantial equivalence to the LifeScan, Inc., OneTouch® Ultra®.

Device Description: The G4™ Monitor is an in vitro diagnostic device designed for measuring the concentration of glucose in capillary whole blood, which is used with the G4™ Test Strips.

The test principle is:

This device is an in vitro diagnostic product intended for the measurement of glucose concentration in human blood. The principle of the test relies upon a specific type of glucose in the blood sample, the dehydrogenase glucose that reacts to electrodes in the test strip. The test strip employs an electrochemical signal generating an electrical current that will stimulate a chemical reaction. This reaction is measured by the Meter and displayed as your blood glucose result.

Intended Use: The G4™ Diabetes Monitoring System is used for the quantitative measurement of glucose level in capillary whole blood as an aid in monitoring the effectiveness of diabetes management in the home and in clinical settings. G4™ System is for

510(k) Summary, Continued

testing outside the body (in vitro diagnostic use only). Testing sites include the traditional fingertip testing along with alternate site testing on the forearm giving it an attractive, nearly painless alternative to the more painful fingertip site. The G4™ Control Solutions are a red liquid which is to be used to check that both the G4™ meter and G4™ test strips are working together properly. It contains a known range of glucose as specified on the vial.

Comparison to Predicate Device: The US Diagnostics, Inc. G4™ Module is substantially equivalent to the other products in commercial distribution intended for similar use. The most notable, it is substantially equivalent to the currently marketed item, the OneTouch® Ultra® by LifeScan, Inc.

Conclusion: The G4™ Blood Glucose Monitoring System is substantially equivalent to the following predicate devices: K024194 – LifeScan, Inc. OneTouch® Ultra®
K984261 – LifeScan, Inc. SURESTEP®
K021513 – Roche Diagnostics Corp. Accu-Chek Advantage

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Edward Letko
Managing Director
US Diagnostics, Inc.
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Suite 218
New York, NY 10010

APR 14 2006

Re: k051651
Trade/Device Name: G4™ Meter, G4™ Test Strips, G4™ Control Solutions
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, CGA, JJX
Dated: March 10, 2006
Received: March10, 2006

Dear Mr. Letko

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K051651

Device Name: G4™

Indications For Use: The G4™ Meter device is used for the quantitative measurement of glucose level in capillary whole blood as an aid in monitoring the effectiveness of diabetes management in the home and in clinical settings. G4™ System is for testing outside the body (in vitro diagnostic use only). Testing sites include the traditional fingertip testing along with alternate site testing on the arm.

The G4™ Test Strips is used for the quantitative measurement of glucose level in capillary whole blood as an aid in monitoring the effectiveness of diabetes management in the home and in clinical settings. G4™ System is for testing outside the body (in vitro diagnostic use only). Testing sites include the traditional fingertip testing along with alternate site testing on the arm.

The G4™ Control Solutions are a red liquid which is to be used to check that both the G4™ meter and G4™ test strips are working together properly. It contains a known range of glucose as specified on the vial.

Prescription Use _____ AND/OR Over-The-Counter Use__X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Page 1 of 1

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